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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,752	10/19/2001	Reinhold Schmieding	P/1493-443	6145
24998	7590	08/23/2007	EXAMINER	
DICKSTEIN SHAPIRO LLP			NAJARIAN, LENA	
1825 EYE STREET NW			ART UNIT	
Washington, DC 20006-5403			PAPER NUMBER	
			3626	
			MAIL DATE	
			DELIVERY MODE	
			08/23/2007	
			PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/981,752	Applicant(s) SCHMIEDING, REINHOLD	
	Examiner Lena Najarian	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 6/8/07. Claims 1-17 remain pending. Claims 1, 8, and 14 have been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application.

(A) Referring to claim 1, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

providing predetermined specifications and conditions of a patient to a provider (col. 5, line 51 – col. 6, line 3 of Filho);

subsequently customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and

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conditions of the patient and of the predetermined surgical procedure to be performed on the patient (col. 5, line 51 – col. 6, line 3 and col. 2, lines 1-14 of Filho).

Filho does not teach loaning, by the provider, graft specific surgical instrumentation to match the specifications of the allograft and the procedure.

Admission discloses loaning, by the provider, graft specific surgical instrumentation to match the specifications of the allograft and the procedure (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(B) Claims 2-4 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

4. Claims 5-6 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of Ramshaw et al. (5,791,907).

(A) Claims 5-6 and 15-17 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) Referring to claim 14, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

providing predetermined specifications and conditions of a patient to a provider (col. 5, line 51 – col. 6, line 3 of Filho);

a customized allograft being sized according to the specifications and conditions of the patient and of the predetermined surgical procedure (col. 5, line 51 – col. 6, line 3 of Filho).

Filho does not disclose arranging for the delivery of the customized allograft for a predetermined surgical procedure and providing technical support and/or customer support to operating personnel before and/or during the performance of the procedure.

Admission discloses arranging for the delivery of the customized allograft for a predetermined surgical procedure (p. 1, lines 12-16 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of arranging for the delivery of the allograft with the motivation of the allograft arrival being within the appropriate time window prior to the surgery (p. 1, lines 12-16 of Specification).

Filho and Admission do not expressly disclose providing, by the provider, technical support and/or customer support to operating personnel before and/or during the performance of the procedure.

Ramshaw discloses providing, by the provider, technical support and/or customer support to operating personnel before and/or during the performance of the procedure (col. 2, lines 39-56 and col. 1, lines 12-24 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Filho and

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Admission. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Claim 7 has not been amended and is therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

6. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), and further in view of Hamada (US 6,425,920 B1).

(A) Referring to claim 8, Filho discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (abstract of Filho):

providing predetermined specifications and conditions of a patient to a provider (col. 5, line 51 – col. 6, line 3 of Filho);

a customized allograft being sized according to the specifications and conditions of the patient and of the predetermined surgical procedure (col. 5, line 51 – col. 6, line 3 of Filho).

Filho does not expressly disclose arranging for the delivery of a customized allograft for a predetermined surgical procedure and customizing, by the provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure, wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure.

Admission discloses arranging for the delivery of a customized allograft for a predetermined surgical procedure and wherein the customized surgical instrumentation kit is loaned to the customer for the performance of the surgical procedure (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the aforementioned features within Filho with the motivation of having the allograft within the appropriate time window prior to the surgery and providing the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

Hamada discloses customizing, by the provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure (col. 1, lines 9-20 of Hamada).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Hamada within Filho and Admission. The motivation for doing so would have been so that the implant is compatible with the instrumentation and procedure (col. 1, lines 9-20 of Hamada).

(B) Claims 9-10 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

7. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), in view of Hamada (US 6,425,920 B1), and further in view of Ramshaw et al. (5,791,907).

(A) Claims 11-12 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Filho (6,089,867) in view of admitted prior art (admission), in view of Hamada (US 6,425,920 B1), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Claim 13 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

Response to Arguments

9. Applicant's arguments filed 6/8/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 6/8/07.

(1) Applicant argues that neither Filho nor Applicant's admitted prior art ("AAPA") discloses, teaches or suggests all limitations of amended independent claim 1. Filho

teaches removal of a tooth portion and not the steps of "providing predetermined specifications and conditions of a patient to a provider," much less "subsequently customizing an allograft..." as in the claimed invention.

(2) AAPA teaches that delivery of the allograft is facilitated by a tissue bank and that, if necessary, instrumentation to be used to perform the procedure may be purchased, leased or borrowed from a provider or another medical facility. Thus, AAPA teaches against the step of "loaning, by the provider, graft specific surgical instrumentation to match specifications of the allograft and the procedure." In AAPA, the "provider" or "another medical facility" is different from the tissue bank that delivers the allograft.

(3) Ramshaw fails to address the deficiencies of Filho and AAPA. Ramshaw teaches an interactive medical system for educating and training personnel in various medical procedures, and not providing predetermined specifications and conditions of a patient to a provider, or customizing allografts, or loaning graft instrumentation to match the specifications of the allograft, as in the claimed invention.

(4) AORN does not rectify the deficiencies of Filho and AAPA. AORN fails to disclose any of the limitations of claims 1 and 7.

(5) Hamada relates to systems and methods for spinal fusion surgery, and not to customizing surgical instrumentation kits specifically designed for use with the customized allografts that are loaned to a customer for surgical procedures, as in the claimed invention.

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(A) In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Also, the Examiner respectfully submits that Filho teaches at col. 5, line 51 – col. 6, line 3 that “due consideration must be given to specific anatomical details of the jaw, including nerves associated therewith, when practicing this invention,” that the “size and shape of the implant to be inserted into the recipient should be evaluated....” and “there should be a pre-measurement of the remaining bone....” As such, it is readily apparent that predetermined specifications and conditions of a patient are provided. Filho also teaches that “if the patient has a mandibular alveolar process measuring 13 mm from the top to bottom, the length of the implant and corresponding opening for receiving the implant should be no longer than about 8 mm....” As such, it is readily apparent that there is a customizing of the allograft to fit the recipient.

(B) As per the second argument, the Examiner respectfully submits that AAPA was relied on to disclose that it is well known for a provider to loan appropriate instruments (p. 1, lines 12-19 of Specification). In addition, there is no language in the claim that requires the provider of the instrument to be the tissue bank (note step 2 of claim 1).

(C) As per the third argument, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(D) As per the fourth argument, the Examiner respectfully submits that AORN was relied on to teach the limitations of claims 7 and 13, not claim 1. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

(E) As per the fifth argument, the Examiner is concerned that, aside from merely alleging that certain claimed features are not obvious from Hamada, Filho, and AAPA, essentially in the form of blanket statements, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out HOW the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Mertizner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

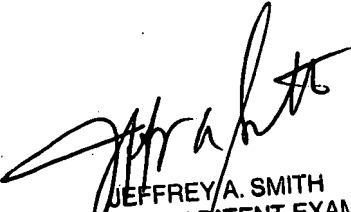
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8-8-07


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